CLINICAL TRIALS UPDATES

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Two-year follow-up results of the SPACE study

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The 2-year results of the Stent-protected Percutaneous Angioplasty vs Endarterectomy of Symptomatic Carotid Artery Stenosis (SPACE) study were recently presented at the 2009 International Stroke Conference of the American Heart Association (San Diego, Calif, Feb 18-20, 2009).[1]

The SPACE study was a multinational randomized controlled trial comparing carotid artery stenting (CAS) with endarterectomy (CEA) in the treatment of patients with symptomatic carotid stenoses. The primary end point was the composite of 30-day rate of stroke or death and was analyzed using a noninferiority test (threshold, 2.5%). The study failed to prove noninferiority for the primary end point in the 1214 randomized patients (absolute difference, 0.47; 95% confidence interval [CI], –2.41 to +3.35; $P = .09$).

In this report, 2-year follow-up information was complete in 88.9% of patients. The 2-year Kaplan-Meier estimates of stroke or death did not differ between the CAS (9.5%) and CEA (8.8%) groups (hazard ratio, 1.10; 95% CI, 0.75-1.61). Recurrent stenosis (≥70%) was significantly more frequent after CAS (hazard ratio, 2.23; $P = .0004$). Patient age was observed to be the only characteristic predictive of periprocedural risk after CAS ($P = .008$) but not CEA ($P = .45$). Patients aged <68 years had a nonsignificant trend of fewer strokes and deaths after CAS (8.8% for CEA vs 4.8% for CAS, $P = .056$). Those aged >68 years had a significantly better outcome after surgery (8.2% for CEA vs 13.4% for CAS, $P = .039$).

Initially, SPACE failed to show noninferiority of CAS compared with CEA. The rates of stroke and death after 2 years did not differ between the CAS and CEA groups, despite an increased rate of restenosis in the CAS group.

COMMENTARY

The initial SPACE report failed to show noninferiority of stenting compared with endarterectomy for symptomatic stenoses, considering periprocedural (<30 days) rates of stroke and death.[2] In this update of results at 2 years, the combined rate of stroke and death continues not to differ between the two treatments. The increased restenosis rate in the stented patients is significant, although the longer-term effects of this have yet to be determined. Subgroup analysis suggests that older patients (>68 years) are best treated with surgery, but the overall influence of patient age is unclear.

As a result of this study, and others, it is apparent that the role of stenting in average-risk patients remains unclear, with unproven advantages.

REFERENCES

1. Ringleb PA, Hennerici M, Stingele R, Jansen O, Eckstein HH, Hacke W for the SPACE Investigators. Stent-protected percutaneous angioplasty vs endarterectomy of symptomatic carotid artery stenosis two year results of the SPACE Study with respect to subgroup analyses. Stroke 2009; 40:3.
2. SPACE Collaborative Group, Ringleb PA, Allenberg J, Bruckmann H, Eckstein HH, Fraedrich G, Hartmann M, et al. 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomized non-inferiority trial. Lancet 2006;368:1239-47.

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